3/9/98

Sent by: Keith
E-mail: kwbe@erols.com

Comment about The CDRH WWW CDRH server:

[Docket No. 97N-0477]RIN 0910-ZA09

In response to the above Docket 97N-0477.
The GMP regulations that manufactures are submitted to should also port over tho remarketers, third party servicers of medical devices. Granted not all of these can be ported over but many should.

Third party servicers should have to show a history and testing documents for their parts. As many third party vendors buy used equipment and strip them down for parts but never do quality testing of any kind or very limited.

The way it is at current the playing field is very slanted for third party remarketers, equipment sales and third party service providers.

We are talking about medical equipment and should only adhere to the highest standards.

Keith
